

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(Case No. 01-496-A)

In application of:

Damian J. Gallina

Serial No: 10/050,655

Filed: January 16, 2002

**For: Compositions and Methods For
Treating Retroviral Infections**

Examiner: R. Winston

Group Art Unit: 1654

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF DAMIAN J. GALLINA, BA, BS, RPh, UNDER RULE 132

Dear Sir,

I, Damian J. Gallina, BA, BS, RPh, declare and state:

1. I am the sole inventor of the invention claimed in the above-identified application and am familiar with the specification, claims, and prosecution history thereof.

2. I received my B.S. degree from The University of Pittsburgh, Pittsburgh, PA in 1970 in the field of Pharmacy, I received my B.A. degree from Edinboro University, Edinboro, PA in 1980 in the fields of Natural Sciences and Mathematics, and I have been a registered pharmacist since 1971.

3. From 1971 to 1976 I was a pharmacist at St. Vincent Hospital and a research scientist at Mercyhurst College, both in Erie, PA. From 1976 to 1986 I was a retail pharmacist, nursing home pharmacist, and Vice President and Chief Science Officer for Cosmos Scientific, Inc. From 1986 to 1998 I was Vice President, Chief Operating Officer, and Chief Scientific Officer of Patent Biopharmaceutics, Inc., based in Baltimore, MD. From 1998 to the present I have been a retail pharmacist for Rite Aid.

4. I founded Surrogate Pharmaceutical Pathways, LLC as a Delaware LLC in 1999 (moved to Erie, PA in 2001) and have been the President and Chief Scientific Officer of Surrogate Pharmaceutical from 1999 to the present.

5. I am currently or have been a member of numerous professional societies, including the American Pharmaceutical Association and The American Cancer Society.

6. I am a named inventor on 11 issued U.S. Patents.

7. I understand that in the Office Action mailed April 6, 2005 for the above-identified application, the claims were rejected as anticipated by Guo (Dissertation Abstracts International, 1996, Vol. 57, No. 1B, p. 225).

8. I understand that claim 54 of the present application recites "[a] composition comprising: a) HIV infected cells that have been treated with hyaluronidase, and b) optionally a pharmaceutically acceptable carrier or diluent, wherein the cells form HIV immunogens or antigens that prime and activate antigen presenting cells."

9. As one of skill in the art, I declare that claim 54 and its dependent claims in the above-identified application are not inherently anticipated by Guo, as the cells of Guo do not form HIV immunogens or antigens that prime and activate antigen presenting cells.

10. I understand that claim 57 of the present application recites "[a] composition comprising: a) HIV infected cells that have been treated with hyaluronidase, and b) optionally a pharmaceutically acceptable carrier or diluent, wherein the HIV infected cells exhibit reduced cell viability."

11. As one of skill in the art, I declare that claim 57 and its dependent claims in the above-identified application are not inherently anticipated by Guo, as the cells of Guo do not exhibit reduced cell viability.

12. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity and/or enforceability of the application and/or any patent issuing therefrom.

Dated: July 5, 2005

By:


Damian J. Gallina, BA, BS, RPh